

CLAIMS

We claim:

1. A method of providing resistance to pannus overgrowth to an implantable prosthetic heart valve comprising:
 - A) providing an implantable heart valve comprising a valve orifice defining a blood flow area, a leaflet coupled to said orifice for movement between an open position and a closed position, and a sewing cuff coupled to said orifice, said sewing cuff comprising a material suitable for retaining an antibiotic;
 - B) providing an antibiotic solution comprising minocycline and rifampin dissolved in a solvent;
 - C) contacting said material suitable for retaining an antibiotic and said antibiotic solution to obtain an antimicrobial reservoir;
 - D) removing the solvent from said antimicrobial reservoir; and
 - E) implanting said heart valve.
2. The method of claim 1 wherein said solvent is methanol.
3. The method of claim 1 wherein said solvent comprises SCO₂.
4. The method of claim 3 wherein said solvent comprises a cosolvent selected from the group consisting of C1 to C6 alcohols, C1 to C6 ethers, C1 to C6 aldehydes, pyrrolidinones, dimethyl sulfoxide, dimethyl formamide, acetonitrile, and acetic acid.
5. A method of providing resistance to pannus overgrowth to an implantable prosthetic heart valve comprising:
 - a) providing a sewing cuff comprising a material suitable for retaining an antibiotic;
 - b) providing an antibiotic solution comprising minocycline and rifampin dissolved in a solvent;
 - c) contacting said material suitable for retaining an antibiotic and said antibiotic solution to obtain a sewing cuff comprising an antimicrobial reservoir;
 - d) removing the solvent from said antimicrobial reservoir;

- e) providing an implantable heart valve comprising a valve orifice having an interior surface defining a flow area, an exterior peripheral surface, and a leaflet coupled to said orifice for movement between an open position and a closed position;
10 f) coupling said sewing cuff to said exterior peripheral surface of said heart valve; and
g) implanting said heart valve.

6. The method of claim 5 wherein said solvent is methanol.

7. The method of claim 5 wherein said solvent comprises SCO₂.

8. The method of claim 7 wherein said solvent comprises a cosolvent selected from the group consisting of C1 to C6 alcohols, C1 to C6 ethers, C1 to C6 aldehydes, pyrrolidinones, dimethyl sulfoxide, dimethyl formamide, acetonitrile, and acetic acid.

9. An implantable prosthetic heart valve having resistance to pannus overgrowth comprising:

a valve orifice comprising an interior surface defining a flow area and an exterior periphery;

5 at least one leaflet coupled to said orifice for movement between an open position and a closed position;

a sewing cuff coupled to said exterior periphery, said sewing cuff comprising a reservoir having rifampin and minocycline incorporated therein.

10. A pannus-resistant implantable prosthetic heart valve, said heart valve being made by a method comprising
providing an implantable prosthetic heart valve;
providing an antimicrobial sewing cuff made by a process comprising
5 providing a porous, hydrophobic reservoir;
providing a diffusable antimicrobial substance effective for inhibiting pannus growth on said heart valve after implantation;
dissolving said diffusable antimicrobial substance in a fluid solvent to form an antimicrobial solution;

- 10 contacting said antimicrobial solution and said porous, hydrophobic reservoir;
precipitating at least a portion of said diffusable antimicrobial substance from said
antimicrobial solution onto said hydrophobic reservoir;
removing said fluid solvent from said reservoir to make an antimicrobial reservoir;
incorporating said antimicrobial reservoir in a sewing cuff to make an antimicrobial
15 sewing cuff; and
coupling said antimicrobial sewing cuff to said implantable heart valve to make a
pannus-resistant implantable prosthetic heart valve.

11. The pannus-resistant implantable prosthetic heart valve of claim 10, wherein
said fluid solvent comprises supercritical carbon dioxide.

12. The pannus-resistant implantable prosthetic heart valve of claim 11, wherein
said precipitating step comprises heating said solution.

13. The pannus-resistant implantable prosthetic heart valve of claim 11, wherein
said precipitating step comprises cooling said solution.

14. The pannus-resistant implantable prosthetic heart valve of claim 11, wherein
said precipitating step comprises lowering the pressure of said fluid solvent below the
critical pressure of carbon dioxide.

15. The pannus-resistant implantable prosthetic heart valve of claim 11, wherein
said fluid solvent additionally comprises at least one cosolvent

16. The pannus-resistant implantable prosthetic heart valve of claim 11, wherein
said fluid solvent additionally comprises at least one surfactant.

17. The pannus-resistant implantable prosthetic heart valve of claim 10 wherein
said diffusable antimicrobial substance comprises rifampin and minocycline.

18. The pannus-resistant implantable prosthetic heart valve of claim 10 or 2 wherein said diffusable antimicrobial substance comprises minocycline.

19. The pannus-resistant implantable prosthetic heart valve of claim 10 wherein said fluid solvent comprises methanol.

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